

Appl. No. 10/866,771

Amendment dated: September 29, 2005

Reply to OA of: April 29, 2005

This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims:

1(previously presented). A metered dose inhaler which comprises a canister fitted with a metering valve which contains a pharmaceutical solution aerosol formulation which comprises:

- (i) fluticasone propionate and
- (ii) a hydrofluoroalkane (HFA) propellant,

characterised in that the fluticasone propionate is completely dissolved in the formulation; wherein the canister is fitted into a channelling device which comprises a mouthpiece actuator having an actuator exit orifice of diameter 0.25mm or less.

2(currently amended). A metered dose inhaler according to claim 1 wherein the formulation comprises:

- (i) fluticasone propionate;
- (ii) a hydrofluoroalkane (HFA) propellant;
- (iii) a low volatility component present in the formulation at a concentration of 0.5 to 3% w/w, to increase the mass median aerodynamic diameter (MMAD) of the aerosol particles on actuation of an inhaler; and
- (iv) a solubilisation agent in sufficient quantity to solubilise the fluticasone propionate in the formulation.

3(previously presented). A metered dose inhaler according to claim 1 wherein the hydrofluoroalkane (HFA) propellant is 1,1,1,2-tetrafluoroethane (HFA134a).

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4(previously presented). A metered dose inhaler according to claim 1 wherein the formulation contains a low volatility component which is glycerol, propylene glycol or polyethylene glycol.

5(previously presented). A metered dose inhaler according to claim 4 wherein the formulation contains a low volatility component which is polyethylene glycol.

6(previously presented). A metered dose inhaler according to claim 4 wherein the formulation contains a low volatility component which is glycerol.

Claim 7(canceled).

8(previously presented). A metered dose inhaler according to claim 1 wherein the formulation comprises:

- (i) fluticasone propionate;
- (ii) 1,1,1,2-tetrafuoroethane (HFA 134a);
- (iii) 0.5-3% (w/w) glycerol; and
- (iv) a solubilisation agent in sufficient quantity to solubilise the fluticasone propionate in the formulation.

9(previously presented). A metered dose inhaler according to claim 1 wherein the formulation contains between 0.8 and 1.6% (w/w) glycerol.

10(currently amended). A metered dose inhaler according to claim 9 wherein the formulation [[which]] contains between 1.0 and 1.6% (w/w) glycerol.

11(previously presented). A metered dose inhaler according to claim 10 wherein the formulation contains between 1.0 and 1.6% (w/w) glycerol.

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12(previously presented). A metered dose inhaler according to claim 10 wherein the formulation contains 1.0% (w/w) glycerol.

13(previously presented). A metered dose inhaler according to claim 1 wherein the concentration of fluticasone propionate in the formulation is 0.025 to 0.15% w/v.

14(previously presented). A metered dose inhaler according to claim 13 wherein the concentration of fluticasone propionate in the formulation is 0.035 to 0.15% w/v.

15(previously presented). A metered dose inhaler according to claim 14 wherein the concentration of fluticasone propionate in the formulation is 0.04 to 0.1% w/v.

16(previously presented). A metered dose inhaler according to claim 13 wherein the concentration of fluticasone propionate in the formulation is 0.025 to 0.04% w/v.

17(previously presented). A metered dose inhaler according to claim 1 wherein a solubilisation agent is present in the formulation which is ethanol or propylene glycol.

18(previously presented). A metered dose inhaler according to claim 1 wherein a solubilisation agent is present in the formulation which is an alkane or ether.

19(previously presented). A metered dose inhaler according to claim 1 wherein a solubilisation agent is present in the formulation which is dimethoxymethane.

20(previously presented). A metered dose inhaler according to claim 1 wherein a solubilisation agent is present in the formulation which is ethylacetate.

21(previously presented). A metered dose inhaler according to claim 17 wherein a solubilisation agent is present in the formulation which is ethanol.

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22(previously presented). A metered dose inhaler according to claim 21 wherein the concentration of ethanol in the formulation is 5 to 30% w/w.

23(previously presented). A metered dose inhaler according to claim 22 wherein the concentration of ethanol in the formulation is 10 to 20% w/w.

24(previously presented). A metered dose inhaler according to claim 22 wherein the concentration of ethanol in the formulation is 7 to 16% w/w.

25(previously presented). A metered dose inhaler according to claim 22 wherein the concentration of ethanol in the formulation is 7 to 11% w/w.

26(previously presented). A metered dose inhaler according to claim 22 wherein the concentration of ethanol in the formulation is 7 to 8% w/w.

27(previously presented). A metered dose inhaler according to claim 19 wherein the concentration of solubilisation agent in the formulation is 14 to 16% w/w.

Claim 28(canceled).

29(previously presented). A metered dose inhaler according to claim 1 comprising as canister an aluminium can which is anodised, lacquer-coated and/or plastic coated.

30(previously presented). A metered dose inhaler according to claim 29 wherein the canister is coated with a fluorocarbon polymer.

31(previously presented). A metered dose inhaler according to claim 1 wherein the canister is fitted with a metering valve of metering volume 100 µl.

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Claim 32(cancelled).

33(previously presented). A metered dose inhaler according to claim 1 wherein the channelling device comprises a mouthpiece actuator having an actuator orifice of diameter 0.15-0.22mm.

34(previously presented). A method of treating respiratory disorders which comprises administration by inhalation of an effective amount of a pharmaceutical aerosol formulation by means of a metered dose inhaler according to claim 1.

35(previously presented). A metered dose inhaler according to claim 20 wherein the concentration of solubilising agent in the formulation is 14 to 16% w/w.

36(previously presented). A metered dose inhaler according to claim 14 wherein the propellant is 1,1,1,2-tetrafluoroethane and a solubilising agent is present in the formulation which is ethanol.

37(previously presented). A metered dose inhaler according to claim 15 where in the propellant is 1,1,1,2-tetrafluoroethane and a solubilising agent is present in the formulation which is ethanol.

38(previously presented). A metered dose inhaler according to claim 36 wherein a low volatility component to increase the mass median aerodynamic diameter (MMAD) of the aerosol particles on actuation of the inhaler is present in the formulation which is glycerol at a concentration of 0.5-3% w/w.

Claim 39(cancelled).